

### **REMARKS/ARGUMENTS**

Reconsideration of this application is requested. Claims 1-13, 20 and 22-27 are pending in the application. These claims all stand rejected as being "obvious" and unpatentable under 35 USC §103(a) over a published U.S. application of Aston (and Canham, one of the joint inventors herein) in combination with various secondary references. The Official Action includes four separate rejections directed to various groupings of claims but applicants regard all four of them to be defective for the reasons stated in more detail below.

First it is important to establish date of availability for the four applied references.

The subject application claims benefit of a GB priority date of May 31, 2002. DeGrado is available as prior art as of March 7, 2002. Lally is available as prior art as of November 27, 2003 and possibly as early as March 13, 2002 but only for the contents of the provisional application no. 60/364,192.

Although the Aston US application (US publication no. 2004/0010313) was published after the priority date of the present invention and does not qualify as a reference under 35 USC §103(c) as Aston and the present application are commonly owned, the corresponding Aston PCT publication, WO 01/95952A, published on 20 December 2001 which is before the priority date of the present invention, could be used as the basis for an obviousness objection under 35 USC §103(a) in view of section 102(a).

In order to advance examination of this application this response will be based on the assumed availability as prior art of WO 01/95952A. The examiner will duly take note of the fact that Professor Canham is an applicant of both the published Aston (plus Canham) application as well as the subject application herein and thus applicants are able to speak with authority as to the content of the cited documents, in particular, the commonly assigned Aston (plus Canham) application which share Professor Canham as a common inventor.

The Examiner asserts that Aston (plus Canham) discloses the preparation of porous blocks comprising bioactive silicon, referring to paragraph [0026], which mentions an orthopedic implant device which may be a fixation block. From this starting point, the Examiner argues that it would be obvious to arrive at the presently claimed invention by combining Aston (plus Canham) with DeGrado (for the self-assembly treatment) to arrive at the subject matter of present claims 1-13, 20 and 22-27, and further with Lee (to arrive at present claims 14-16), Lally

(for claims 17-19) *or* Nonami (to arrive at present claim 21).

Applicants respectfully submit that the Examiner's characterization of the teaching of Aston (plus Canham) is incorrect. It is clear from reading Aston that the "block" referred to in paragraph [0026] is entirely different from the scaffold assembly of the present invention comprising a plurality of blocks self-assembled together. The "block" referred to in paragraph [0026] of Aston (corresponding to page 7, line 13 of the published PCT specification) is simply a block of material whose purpose is to fix two structures together; there is no suggestion that it is formed from multiple blocks of porous silicon. Thus, "block" is used in an entirely different sense in the two specifications. It appears that the Examiner has seen that the word "block" is used in both cases and has concluded that the two inventions are the same without giving any thought to the underlying context.

Aston neither teaches nor suggests a scaffold comprising multiple blocks of porous silicon treated so as to adhere together in self-assembly. As discussed at page 6 of the present specification, in contrast to Aston, the present invention advantageously affords the possibility of obtaining the larger scaffolds needed for most bone grafts with the desired nanostructure throughout. Furthermore, the scaffolds of the present invention have highly ordered structures which, for bone grafts, translates into excellent control of macroporosity and macropore architecture. These advantages would not be apparent from Aston and there would be no motivation, starting from Aston, to arrive at the presently claimed invention.

Combining Aston with DeGrado does not overcome the deficiencies of Aston.

Considering DeGrado, applicants note that this is concerned with amphiphilic polymers as anti-infective agents. The attachment of these polymers to solid surfaces is described and in paragraph [0152] the bonding of monolayers to solid supports to give stable, uniformly packed molecular layers that self-assemble by absorption is discussed. There is, however, no suggestion of self-assembly of blocks and nothing to suggest to the average skilled reader that DeGrado is in any way relevant to the preparation of improved orthopedic scaffolds.

Applicants therefore submit that there would be no motivation for combining Aston with DeGrado and that even if these two references were combined, there would be no possibility of arriving at the presently claimed invention. Again, it seems that the Examiner has alighted on the presence of the words "self-assembly" in the text of DeGrado, noted that these words are also

used in the present invention and has concluded (incorrectly) that DeGrado is therefore relevant without proper consideration of the context.

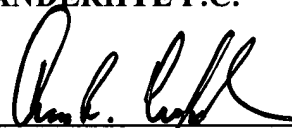
None of the remaining references cited additionally by the Examiner overcome the deficiencies of Aston and DeGrado and applicants submit, therefore, that these are irrelevant. There is nothing in the disclosures of Lee, Lally or Nomani to disclose or suggest the self-assembly of a scaffold comprising two or more blocks of bioactive material treated so as to adhere together.

For the above reasons it is respectfully submitted that all pending claims are directed to patentable subject matter. Reconsideration and allowance are solicited. Should the examiner require further information, please contact the undersigned.

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

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